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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,201	05/26/2000	J. Michael McIntosh	2314-187	-8265

6449 7590 05/23/2002

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EXAMINER

BUGAISKY, GABRIELE E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/23/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/580,201

Applicant(s)

MCINTOSH ET AL.

Examiner

Gabriele E. BUGAISKY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 15-18,27,28,30 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,11-12, 19-26 is/are rejected.
- 7) ☒ Claim(s) 2-10,13,14 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I and SEQ ID NO:2 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that if the members of the group are sufficiently few in number or so closely related that a search can be made with serious burden, all claims must be examined. Applicants state that there is no serious burden. This is not found persuasive because the 14 amino acid generic sequence of SEQ ID NO:1 contains 9 Xaas (variable amino acids) Xaa may be any of 4 amino acids, Xaa0 may any of 12 specific amino acids, Xaa 1 may be any of 10 specific amino acids, Xaa2 may be any of 16 specific amino acids OR "any synthetic aromatic amino acid" OR "an aliphatic amino acid bearing linear or branched hydrocarbon chains. . . OR non-natural derivatives of the aliphatic amino acid", Xaa3 may be any of 14 specific amino acids OR any synthetic basic amino acid OR any hydroxylated synthetic residue, etc. If one includes only the specifically recited amino acid variables, one is left with a minimum of $4 \times 12 \times 10 \times 16 \times 14 \times 17 \times 21 \times 3 \times 13 \approx 1.5 \times 10^9$ defined peptides to search. This is clearly an incredible search burden.. Applicant has not argued the restriction with respect to Groups I-IV.

The requirement is still deemed proper and is therefore made FINAL.

In reviewing the application, the Examiner has included SEQ ID NO:3 for consideration, as it is but a single amino acid truncation of SEQ ID NO:2.; SEQ ID NO:12 has also been considered as it is the propeptides for both SEQ ID Nos: 2 and 3.

Claims 15-18, 27-28 and 30-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention,

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The listing of references in the specification (pages 31-33) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The references submitted with the copy of the protest that accompanied the response of 12/01 have been considered.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (e.g., page 1, lines 26-27, page 2, line 5, page 6, line 11, etc.). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The term "may be substituted" does not appear to limit the potential substitutions to those recited.

Claims 2-12 and 29 are objected to because of the following informalities: they read upon non-elected subject matter. Appropriate correction is required.

Claim 2 is also objected to because of the following informalities: line 1 recites "seleceted". This should presumably be "selected". Appropriate correction is required.

Claim 12 is also objected to because of the following informalities: line 4 recites "homoargine". This should presumably be "homoarginine". Appropriate correction is required

Claim 24 is objected to because of the following informalities: line 1 recites "... conotoxin peptided" This should presumably be "... Conotoxin peptide . . ." Appropriate correction is required.

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 11-12 and 19-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1 and 11-12, the phrase "such as" (lines 9, 14, 18) renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 11-12, the term "e.g." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.5(d).

Further, with respect to claim 12

With respect to claim 1, it is not clear what is encompassed by "hydroxyl Ted synthetic residue" of lines 12-13; or how what distinction is to be made in claims 1 and 12 between a "synthetic" amino acid and a "non-natural derivative" of an amino acid. Furthermore, how is, e.g., a synthetic phenylalanine distinguishable from a naturally occurring phenylalanine?

Claims 19-26 are included in this rejection as they ultimately depend from claim 1 and do not clarify the ambiguity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 11-12 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5885797 (Chen *et al.*) The reference reveals the sequence of mouse transcription factor I-mf, which contains at positions 203-212 the sequence CCGSGECADC. It is deemed anticipatory for the claimed subject matter because the above protein can be considered a derivative of SEQ ID NO:2 as it retains the core sequence of SEQ ID NO 1: CCGXXXCXXC.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Gabriele E. Bugaisky, Ph.D. whose telephone number is (703) 308-4201. The Examiner can normally be reached from 8:15 AM to 12:15 PM on Mondays and from 8:15 AM to 1:15 PM on other weekdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1.

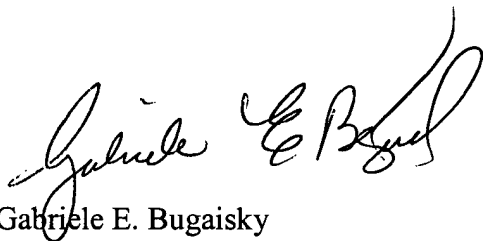
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The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Gabriele E. Bugaisky". The signature is fluid and cursive, with the first name "Gabriele" written in a larger, more prominent script than the last name "Bugaisky".

Gabriele E. Bugaisky
Patent Examiner
May 18, 2002

**GABRIELLE BUGAISKY
PATENT EXAMINER**